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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/935,703 | 08/24/2001 | Yanggu Shi | PT050P1 | 9669 |

22195 7590 12/04/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
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EXAMINER

RAMIREZ, DELIA M

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary**Application No.**

09/935,703

Applicant(s)

SHI ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,13,17-20 and 22-42 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,17-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Claims 12-13, 17-20, 22-42 are pending.

It is noted that no list of claims showing amendments to the claims have been submitted in response to an Office Action (Paper No. 8) mailed on 6/26/2003. As such, it is assumed that the latest version of the claims is that submitted on 6/2/2003.

Applicant's response under 37 CFR 1.111 and a copy of the ATCC deposit receipt for accession number PTA1452, filed on 9/26/2003 is acknowledged.

This application contains claims 12-13, 17-20, and 22 drawn to an invention non-elected with traverse in Paper No. 7, filed on 6/2/2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 101

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 23-42 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility.
3. Claims 23-42 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.
4. These rejections have been discussed at length in Paper No. 8, mailed on 6/26/2003.

5. Applicants argue that the utility rejection is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by Applicants in the written description of the invention. Applicants also submit that the utility rejection is improper if a person of ordinary skill in the art would know how of a use for the claimed invention at the time the application was filed. It is Applicant's contention that the Examiner has to provide evidence sufficient to show that a statement of asserted utility would be considered false by a person of ordinary skill in the art. Applicants submit that the identity of about 33% and similarity of about 61% in the catalytic domain of murine tyrosine phosphatase would allow one of skill in the art to reasonably conclude that the claimed invention was also a tyrosine phosphatase. In addition, Applicants submit that the polynucleotides claimed can be used for breast cancer diagnosis and that this diagnostic utility combined with the expression of the claimed polynucleotides in breast cancer is sufficient to satisfy the 35 USC 101 utility requirement.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the utility rejection. It is noted that credibility is not been assessed herein. Instead, as indicated in the previous Office Action, the invention was deemed as lacking a substantial and specific utility for the following reasons. While the polypeptide of SEQ ID NO: 7 has been disclosed as encoding a protein tyrosine phosphatase, this polypeptide is only 67 amino acids long and the art indicates that tyrosine phosphatases have at least one catalytic domain of approximately 240 amino acids. See the teachings of Neel et al. as indicated in previous Office Action Paper No. 7. Furthermore, the closest homolog disclosed in the specification (BAA23761, Ohsugi et al.) having protein tyrosine phosphatase activity is 426 amino acids. In addition, while Applicants have based the assertion of function based on structural homology, the art does not appear to support Applicant's assertion of function for the polypeptide of SEQ ID NO: 7 since the closest homolog with protein tyrosine phosphatase activity (BAA23761) is at best 32.8% sequence homologous to the polypeptide of SEQ ID NO: 7 and the region of homology

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corresponds to only 15 amino acids of the mouse protein tyrosine phosphatase's catalytic domain. Also, the specification is completely silent in regard to substrate specificity of the polypeptide of SEQ ID NO: 7 nor does it provide any information as to the biological processes associated with this polypeptide. In view of the evidence presented by the Examiner in previous Office Action Paper No. 7, it is unclear as to how one of skill in the art can reasonably conclude that a polypeptide of 67 amino acids can have protein tyrosine phosphatase activity if (1) the catalytic domain, which is essential for enzymatic activity, of a protein tyrosine phosphatase is approximately 240 amino acids long, (2) the closest protein tyrosine phosphatase homolog cited in the specification is 426 amino acids long, further supporting the teachings of Neel et al. in regard to the minimum size required to display protein tyrosine phosphatase activity, and (3) the closest protein tyrosine phosphatase homolog is at best 32.8% sequence homologous to the polypeptide of SEQ ID NO: 7 and the region of homology corresponds to only 15 amino acids of the mouse protein tyrosine phosphatase's catalytic domain. Therefore, the asserted utility is not specific since there is no information as to the substrate specificity and/or biological processes associated with the polypeptide of SEQ ID NO: 7, nor is the asserted utility substantial since in the absence of experimental evidence corroborating Applicant's assertion of activity for the polypeptide of SEQ ID NO: 7, and in the absence of any information as to the substrate specificity or the biological processes associated with this polypeptide, one of skill in the art would have to carry out further research to determine if the claimed polynucleotides encode a protein tyrosine phosphatase as well as the substrates/biological processes associated with the polypeptide of SEQ ID NO: 7.

In regard to arguments that the claimed polynucleotides can be used for breast cancer diagnosis and that this diagnostic utility combined with the expression of the claimed polynucleotides in breast cancer is sufficient to satisfy the 35 USC 101 utility requirement, this argument is not found persuasive in view of the complete lack of information as to how these polynucleotides can have a "real world" and specific use in breast cancer diagnostics. The specification is completely silent in regard to (1) which

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types of breast cancer can be detected with the claimed polynucleotides, or (2) levels of expression indicative of breast cancer. Also, no evidence has been presented which would indicate that the claimed polynucleotides are not found in normal breast tissue, such that one can rule out false positives. The utility in breast cancer diagnostics is not deemed substantial since determining the information required to use the claimed polynucleotides as markers of breast cancer would require further research. In addition, since it is well known in the art that there are many types of breast cancers, this utility is not specific since the specification is completely silent in regard to the specific breast cancer that can be detected with the claimed polynucleotides. Therefore, for the reasons set forth above and those of record, one cannot reasonably conclude that the claimed invention has met the utility requirements set forth in 35 USC 101.

Claim Rejections - 35 USC § 112, First Paragraph

7. Claims 33-42 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement since there was no indication in the specification as to public availability of the biological deposit ATCC PTA1452.
8. Applicant's submission of a statement indicating that all restrictions on the availability to the public of ATCC Accession No. PTA1452 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 CFR 1.808(b), is deemed sufficient to overcome the instant rejection, which is hereby withdrawn.

Conclusion

9. No claim is in condition for allowance.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
November 25, 2003

Delia M. Ramirez
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